

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application:

Michael E. Jung *et al.*

U.S. Application No.: 10/590,445

Confirmation No.: 6734

Filed: August 24, 2006

Title: METHODS AND MATERIALS FOR
ASSESSING PROSTATE CANCER
THERAPIES AND COMPOUNDS

Art Unit: 4131

Examiner: Savitha M. RAO

Atty. Dkt. No.: 58086-235854

Customer No.

26694

PATENT TRADEMARK OFFICE

RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a response to the Restriction Requirement dated June 5, 2008 (herein, "Restriction Requirement"), providing for a response time of one month or 30 days, whichever is longer. Applicants, by their attorneys, respond to the Restriction Requirement by electing with traverse as follows.

Remarks and Election in Response to the Restriction Requirement

For clarity, Applicants reiterate the Examiner's view of distinct inventions as expressed in the Restriction Requirement:

Group I. Claims 1-2 and 7-10;
Group II. Claims 3-6; and
Group III. Claims 11-14.

Election

In light of the requirement to elect despite traversal, Applicants elect Group I, i.e., claims 1-2 and 7-10, with traverse.

Traverse

Applicants maintain that restriction to one of Group I (claims 1-2 and 7-10), Group II (claims 3-6), and Group III (claims 11-14) is improper. Applicants understand that the Examiner views the common technical feature linking the claims as being the compound claimed in Group I, a thiohydantoin. Applicants further understand that the Examiner views this thiohydantoin compound as being shown in the prior art, so that it is not a special technical feature under PCT Rule 13.2. Applicants maintain that the thiohydantoin compound is not shown in the prior art, and, therefore, argue that Group I, Group II, and Group III relate to a single general inventive concept as required by Patent Cooperation Treaty (PCT) Rule 13.1.

The Examiner indicates that thiohydantoins like those claimed in Group I of the instant application are shown in columns 1 and 2 of U.S. Patent No. 6,087,509 to Claussner et al. (herein, "Claussner '509"). This is not accurate. Claussner does not present a compound that has an azide functional group, N₃, as does the thiohydantoin compound of Group I. For example, lines 25-34 of column 1 of Claussner '509 do not list azide as a radical that can be substituted on a group R₃.

The above-identified application is a national phase application of the international application PCT/U2005/005529. Copies of the International Preliminary Report on Patentability (IPRP) and the International Search Report and Written Opinion received for this international application are included with the present Response. The International Search Report cited U.S. Patent Nos. 5,750,553 to Claussner et al. and 5,656,651 to Sovak et al. and concluded that neither document was considered to be of particular relevance ("A" reference). The Written Opinion indicated that all claims 1-14 met the requirements of novelty, inventive step, and industrial applicability, "because the prior art does not teach or fairly suggest the claimed compositions." As in the case of Claussner '509, U.S. Patent No. 5,750,553 to Claussner et al. does not list azide as a radical that can be substituted on a group R₃.

The Examiner notes on page 3 of the Restriction Requirement that the thiohydantoin compound claimed in Group I is a common technical feature linking Group I (claims 1-2 and 7-10), Group II (claims 3-6), and Group III (claims 11-14) of the above-identified application. This thiohydantoin compound was not shown in the prior art and represents a contribution over the prior art and is therefore a special technical feature establishing a technical relationship among Group I, Group II, and Group III, according to PCT Rules 13.1 and 13.2. Therefore, unity of invention among the claims of Group I (claims 1-2 and 7-10), Group II (claims 3-6), and Group III (claim 11-14) is present, and no restriction should be required. For these reasons, Applicants respectfully traverse the Examiner's requirement to elect one of Group I, Group II, and Group III, and request that the requirement of restriction be withdrawn.

Applicants expressly reserve the right to rejoin any claims withdrawn following this Response.

Republication error


Applicants note that the April 17, 2008 Republication of the above-identified application as US 2008/0090888 A2 contains a printing error in the left-hand column of page 13, for claim 1. The Republication contains the text "wherein R is $(\text{CH}_2)_n\text{N}_3$ or N_3CH_4 ". The text should be "wherein R is $(\text{CH}_2)_n\text{N}_3$ or $\text{N}_3\text{C}_6\text{H}_4$ ". Applicants note that this text was correctly printed in the preceding Publication US 2007/0191443 as well as in the International Publication No. WO 2005/099693. While recognizing that the Examiner is not responsible for publication matters, Applicants are concerned that following submission of a Request for Republication, the PTO introduced a new printing error in the Republication not present in the preceding Publication. To avoid the need for a further republication request, Applicants respectfully request that the Examiner note that claim 1 should correctly state "wherein R is $(\text{CH}_2)_n\text{N}_3$ or $\text{N}_3\text{C}_6\text{H}_4$ ".

Applicants respectfully request that a Notice of Allowance of all pending claims, i.e., claims 1-14, be timely issued in this case.

No fee is believed to be necessary in connection with the filing of this Response to Restriction Requirement. However, the Commissioner is authorized to charge any fee deemed necessary or credit any overpayment found to Deposit Account No. 22-0261.

Respectfully submitted,

Dated: July 7, 2008



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DC2/967782

From the INTERNATIONAL BUREAU

PCTNOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION
TREATY)

(PCT Rule 44bis.1(c))

To:

OLDENKAMP, David, J.
Shapiro & Dupont LLP
233 Wilshire Boulevard
Suite 700
Santa Monica, CA 90401
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)

08 September 2006 (08.09.2006)

Applicant's or agent's file reference

0180.0077

IMPORTANT NOTICE

International application No.

PCT/US2005/005529

International filing date (day/month/year)

23 February 2005 (23.02.2005)

Priority date (day/month/year)

24 February 2004 (24.02.2004)

Applicant

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

COMPUTER UPDATED

10/18/06

JH

JCH

10/18/06

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 0180.0077	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2005/005529	International filing date (<i>day/month/year</i>) 23 February 2005 (23.02.2005)	Priority date (<i>day/month/year</i>) 24 February 2004 (24.02.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant THE REGENTS OF THE UNIVERSITY OF CALIFORNIA		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Date of issuance of this report 30 August 2006 (30.08.2006) Authorized officer <div style="text-align: right; font-weight: bold;">Yolaine Cussac</div> e-mail: pt11@wipo.int
---	--

PATENT COOPERATION TREATY

REC'D 14 NOV 2005

WIPO

PCT

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:
DAVID J. OLDENKAMP
SHAPIRO & DUPONT LLP
233 WILSHIRE BOULEVARD, SUITE 700
SANTA MONICA, CA 90401

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **10 NOV 2005**

FOR FURTHER ACTION
See paragraph 2 below

Applicant's or agent's file reference

0180.0077

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US05/05529

23 February 2005 (23.02.2005)

24 February 2004 (24.02.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61K 31/415 and US Cl.: 514/396, 398, 399

Applicant

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Date of completion of this opinion

28 October 2005 (28.10.2005)

Authorized officer

Cybil DeLacroix-Muirheid

Telephone No. (571) 272-1600

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US05/05529

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/05529

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-14</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>1-14</u>	YES
	Claims <u>NONE</u>	NO
Industrial applicability (IA)	Claims <u>1-14</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-14 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the claimed compositions and pharmaceutical composition comprising the described chemical formula as well as the claimed uses of the compositions for inhibiting the growth of prostate cancer cells or a method of inhibiting prostate specific antigen production in a prostate cancer cell. The prior art also fails to disclose or fairly suggest the claimed methods of making the compositions/pharmaceutical compositions as well as methods for antagonizing the function of the ligand binding domain of the androgen receptor polypeptide in a prostate cancer cell.

Claims 1-14 meet the criteria set out in PCT Article 33(4), because the subject matter can be made or used in industry.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
DAVID J. OLDENKAMP
SHAPIRO & DUPONT LLP
233 WILSHIRE BOULEVARD, SUITE 700
SANTA MONICA, CA 90401

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing
(day/month/year) **10 NOV 2005**

Applicant's or agent's file reference
0180.0077

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.
PCT/US05/05529

International filing date
(day/month/year) 23 February 2005 (23.02.2005)

Applicant
THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70.

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until **30 months** from the priority date (in some Offices even later); otherwise, the applicant must, within **20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/ US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (703) 305-3230

Authorized officer

Cyille Delacroix-Muirheid

Telephone No. (571) 272-1600

Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

2 MONTH REMINDER _____
1 MONTH REMINDER _____
2 WEEK REMINDER _____
3 DAY REMINDER _____
ACTION DUE AND DATE _____

NOV 15 2005

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 0180.0077	FOR FURTHER ACTION <small>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</small>	
International application No. PCT/US05/05529	International filing date (<i>day/month/year</i>) 23 February 2005 (23.02.2005)	(Earliest) Priority Date (<i>day/month/year</i>) 24 February 2004 (24.02.2004)
Applicant THE REGENTS OF THE UNIVERSITY OF CALIFORNIA		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the Report

a. With regard to the **language**, the international search was carried out on the basis of:



the international application in the language in which it was filed.



a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II)

3. ☐ **Unity of invention is lacking** (See Box No. III)

4. With regard to the **title**,



the text is approved as submitted by the applicant.



the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,



the text is approved as submitted by the applicant.



the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. _____



as suggested by the applicant.



as selected by this Authority, because the applicant failed to suggest a figure.



as selected by this Authority, because this figure better characterizes the invention.

b. ☒ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/05529

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 31/415

US CL : 514/396, 398, 399

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 514/396, 398, 399

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

STN: registry, structure search, prostate cancer, tumor, neoplasm, carcinoma

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,750,553 A (CLAUSSNER et al.) 12 May 1998 (12.05.1998), see entire document.	1-14
A	US 5,656,651 A (SOVAK et al.) 12 August 1997 (12.08.1997), see entire document.	1-14

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

28 October 2005 (28.10.2005)

Date of mailing of the international search report

10 NOV 2005

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3220

Authorized officer

Cybillé Delacroix-Muirhead

Telephone No. (571) 272-1600

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
DAVID J. OLDENKAMP
SHAPIRO & DUPONT LLP
233 WILSHIRE BOULEVARD, SUITE 700
SANTA MONICA, CA 90401

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 0180.0077		Date of mailing (day/month/year) 10 NOV 2005
FOR FURTHER ACTION See paragraph 2 below		
International application No. PCT/US05/05529	International filing date (day/month/year) 23 February 2005 (23.02.2005)	Priority date (day/month/year) 24 February 2004 (24.02.2004)
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61K 31/415 and US Cl.: 514/396, 398, 399		
Applicant THE REGENTS OF THE UNIVERSITY OF CALIFORNIA		

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Date of completion of this opinion 28 October 2005 (28.10.2005)	Authorized officer Cybille Delacroix-Muirheid Telephone No. (571) 272-1600
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Form PCT/ISA/237 (cover sheet) (April 2005)

written opinion

2 MONTH REMINDER	12/10/05
1 MONTH REMINDER	11/10/05
2 WEEK REMINDER	11/24/06
3 DAY REMINDER	11/11/06

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US05/05529

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US05/05529

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-14</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>1-14</u>	YES
	Claims <u>NONE</u>	NO
Industrial applicability (IA)	Claims <u>1-14</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-14 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the claimed compositions and pharmaceutical composition comprising the described chemical formula as well as the claimed uses of the compositions for inhibiting the growth of prostate cancer cells or a method of inhibiting prostate specific antigen production in a prostate cancer cell. The prior art also fails to disclose or fairly suggest the claimed methods of making the compositions/pharmaceutical compositions as well as methods for antagonizing the function of the ligand binding domain of the androgen receptor polypeptide in a prostate cancer cell.

Claims 1-14 meet the criteria set out in PCT Article 33(4), because the subject matter can be made or used in industry.

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How? Either by cancelling one or more entire claims, adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

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The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.